DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

May 7, 1999

CERTIFIED - RETURN RECEIPT REQUESTED

Mr. John M. Lawson, President
Milner Rushing Discount Drugs
869 Florence Boulevard
Florence, AL 35630

Dear Mr. Lawson:

WARNING LETTER - 99-NSV-13

During an inspection of your oxygen gas repacking facility on April 12 and 14, 1999 our investigators documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The inspection revealed a failure to calibrate your [redacted] with a certified nitrogen gas, inadequate GMP training of personnel, failure to maintain an approved master label, incomplete batch production records, inadequate Standard Operating Procedures (SOPs) and insufficient calibration of equipment used during your filling operation.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Until the violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure and/or injunction, without further notice.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct the noted deviations, including an explanation of each step being taken to prevent the recurrence of similar violations.

If corrective action cannot be taken within fifteen (15) working days, state the reason for the delay and the time within which the correction will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,

Howard E. Lewis
Acting Director
Nashville District

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